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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,144	06/09/2005	Wieslaw Mieczyslaw Kazmierski	PU4962USw	1348
23347	7590	12/26/2008		
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			EXAMINER GALLIS, DAVID E	
			ART UNIT 1625	PAPER NUMBER
			NOTIFICATION DATE 12/26/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/538,144	<b>Applicant(s)</b> KAZMIERSKI ET AL.	
	<b>Examiner</b> DAVID E. GALLIS	<b>Art Unit</b> 1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 42-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☒ Claim(s) 1-3 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/9/05</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

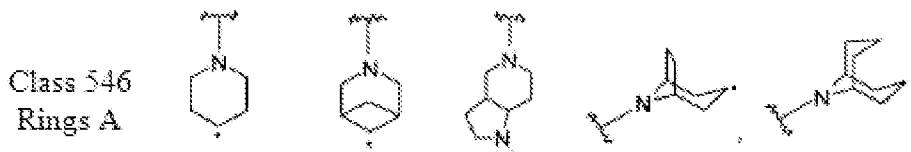
1. Claims 1 through 54 are pending. Claims 42 through 54 have been withdrawn from consideration. Claims 4, 7, 9, 11, 19 through 21, 23, 24, and 36 have been amended. Claims 55 through 61 have been canceled. Applicants' claim to priority from provisional application 60/433,634 filed December 13, 2002 is acknowledged.

### *Election/Restrictions*

2. Applicants' election of Group III, claims 1 through 41 is acknowledged. Applicant states that election was made with traverse, however, no arguments are presented against the restriction requirement. Therefore, the election is hereby MADE FINAL.

The subject matter for the elected Group III is as follows:

III. Claims 1 through 41, drawn to compounds of formula (I) and pharmaceutical compositions thereof, comprising a ring A functionality shown below from class 546 and various subclasses.



### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 3, 4, 5, 10, 14, 18, 19 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Biel (US 3,334,106, August 1, 1967, cited by Applicants), Elpern (US 2,773,870, December 11, 1956, cited by Applicants), Hermans et al. (US 3,539,580, November 10, 1970, cited by Applicants), Ask et al. (US 5,360,805, November 1, 1994 and US 5,968,953, October 19, 1999), Burkholder et al. (Bioog. Med. Chem. Lett., 1997, 7(19), 2531-2536), Taveras (WO98/57962, December 23, 1998) and Tulshian et al. (WO00/06545, February 10, 2000).

5. Biel clearly anticipates claims 1, 2, 3, 4, 10, 14, 19 and 22 teaching a compound of formula (I) wherein A = piperidinyl, n=0, X=-C(O)-, R<sup>1</sup> = phenyl, and R<sup>3</sup>-(Y)<sub>m</sub> = H (see column 6, line 5). Burkholder et al. teach the same compound as Biel (see page 2532, compound 6i; and page 2533, Table 1, compound 7i)

6. Elpern clearly anticipates claims 1, 2, 3, 4, 5, 18, 19 and 22 teaching compounds of formula (I) wherein A = piperidinyl, n=0, X= ethoxy, ethoxymethyl, and propoxymethyl, R<sup>1</sup> = phenyl, and R<sup>3</sup>-(Y)<sub>m</sub> = CH<sub>3</sub> (see column 3, EXAMPLE 1; column 5, EXAMPLE 7; column 6, EXAMPLE 8).

7. Hermans et al. clearly anticipates claims 1, 2, 3, 4, 5, 10, 18, 19 and 22 teaching compounds of formula (I) wherein A = piperidinyl, n=0, X= ethoxy and propoxy, R<sup>1</sup> = unsubstituted and Cl or CF<sub>3</sub> substituted phenyl, and R<sup>3</sup>-(Y)<sub>m</sub> = phenyl substituted and anilinyI substituted C<sub>2</sub> or C<sub>3</sub> alkyl (see all compounds of R<sub>1</sub> = piperidinyl in table starting at columns 21 and 22).

8. Ask et al. clearly anticipates claims 1, 2, 3, 4, 10, 14, 19 and 22 teaching compounds of formula (I) wherein A = piperidinyl, n=0, X=-C(O)-, R<sup>1</sup> = phenyl, and R<sup>3</sup>-

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$(Y)_m = -(CH_2)_5Me$ ,  $-(CH_2)_4OEt$  and  $-(CH_2)_2CH(Ph)(OH)$  (see US5360805, column 5, Table 1, compounds 8 and 11; see US5968953 column 4, compound VI and column 11, line 30).

9. Taveras clearly anticipates claims 1, 2, 3, 14, 19 and 22 teaching a compound of formula (I) wherein A = piperidinyl,  $n=1$ ,  $X = -C(O)CH_2-$ ,  $R^1 = methyl$ ,  $R^2 = carbocyclyl$ , and  $R^3-(Y)_m = -SO_2CH_3$  (see page 49, EXAMPLE 1).

10. Tulshian et al. clearly anticipates claims 1, 2, 3, 4, 10, 14, 19 and 22 teaching a compound of formula (I) wherein A = piperidinyl,  $m=0$ ,  $n=0$ ,  $X = -C(O)-$ ,  $R^1 = phenyl$ , and  $R^3 = CH(Ph)_2$  (see page 25, Table 1, 4<sup>th</sup> entry).

11. Claims 6 through 9, 11 through 13, 15 through 17, 20, 21 and 23 through 41 are rejected due to their dependency on rejected base claims.

12. Clearly formula (I) compounds where A = piperidinyl are known and therefore arguments can be made that the other elected Class 546 Ring A substituents are obvious variants to piperidinyl. It is strongly suggested that Applicants limit the claimed subject matter to the preferred embodiment of the invention as described in the instant disclosure (page 31, line 21 through page 32, line 17). This is also consistent with instant claim 22. In addition to limiting the A ring of the formula (I) compounds, the search is burdensome with copious diverse substituent groups. It is likewise suggested that  $R^1$ ,  $R^2$ ,  $R^3$ , X, and Y groups be limited to those of the preferred embodiment, thus avoiding any potential of further restriction.

***Claim Objections***

13. Claims 1, 2, 3, and 19 are objected to as containing non-elected subject matter with respect to ring A characteristics. Ring A is restricted to the ring systems illustrated above. Correction to the claims is required.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David E. Gallis whose telephone number is 571-272-9068. The examiner can normally be reached on Mon-Thur 8:30-7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David E. Gallis  
Patent Examiner

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/ Bernard Dentz/

Primary Examiner, Art Unit 1625